K041381

SEP 10 2004

Medtronic
XOMED

Summary of 510(k) Submission

Name and address of submitter

Medtronic Xomed Inc.
6743 Southpoint Drive North
Jacksonville, Florida 32216
Contact: David S. Dodd
Phone: (904) 332-8746
Date Prepared: May 24, 2004

Identification of Devices

- Trade name: MeroPack™ Nasal Packing and Sinus Stent.
- Common or usual name: Ear, Nose and Throat Packing, Dressing, and/or Stent
- Classification Name: Intranasal Splint (per 21 CFR §874.4780)
- FDA Classification: Class I - Non-Exempt.

Predicate Device

- MeroGel™ Nasal Dressing and Sinus Stent, and
- Seprapack/Sepragel (Genzyme)

Description of Device

MeroPack™ is a sterile bioresorbable nasal dressing and sinus stent composed of lyophilized and compressed HYAFF® and Collagen. When placed appropriately, MeroPack™ absorbs fluid and swells, conforming to the nasal cavity and creating a tamponade effect that helps to control the minimal bleeding normally associated with routine sinus surgery. The stent gradually degrades over time and is slowly absorbed within 14 days, or it may be aspirated from the cavity earlier at the discretion of the physician.

Indications For Use

MeroPack™ Bioresorbable Nasal Dressing and Sinus Stent is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces during mesothelial cell regeneration in the nasal cavity; to help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and to prevent lateralization of the middle turbinate during the postoperative period.

K041381

Summary of 510(k) Submission, Continued

Substantial Equivalence table:

	Predicate Device: Seprapack / Sepragel	**Predicate Device:** MeroGel™ Nasal Dressing and Sinus Stent	**Proposed Device:** **MeroPack™ Nasal Packing and Sinus Stent**
Intended Use	Post-op, help control minimal bleeding and separate mucosal surfaces / adhesion prevention	Post-op, help control minimal bleeding and separate mucosal surfaces / adhesion prevention	Post-op, help control minimal bleeding and separate mucosal surfaces / adhesion prevention
Indications	nasal/sinus surgery	nasal/sinus surgery	nasal/sinus surgery
Material / Construction	Chemically modified hyaluronic acid and carboxymethylcellulose	esterified hyaluronic acid	esterified hyaluronic acid and collagen
Absorbent Qualities	unknown	in excess of 10 times weight of the device	in excess of 10 times weight of the device
Sterility	gamma irradiation	gamma irradiation	gamma irradiation
Resorption time	7-10 days	approx. 14 days	Within 14 days
Biocompatibility	ISO 10993-1	ISO 10993 1	ISO 10993 1 and FDA Guidance G95-1
Method of Action	hygroscopic, forms gelatinous mass in contact with fluids	hygroscopic, forms gelatinous mass in contact with fluids	hygroscopic, forms gelatinous mass in contact with fluids
Method of Removal	gentle irrigation of residues	gentle irrigation of residues	gentle irrigation of residues

Conclusions drawn from studies

Validity of Scientific Data	Studies were conducted both by a contract laboratory and by in-house laboratories; all followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.
Substantial Equivalence	The data presented in this Premarket Notification support that the subject device is safe and effective and performs in the same manner as the predicate devices when used in accordance with the labeled directions for use and for the requested indication.
Risk and Benefits	The risks of the subject device, as well as the benefits to the patient, are the same as those normally attributed to the use of a space occupying nasal dressing/stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 10 2004

Medtronic Xomed
c/o David S. Dodd
Sr. Regulatory Affairs Specialist
6743 Southpoint Drive North
Jacksonville, FL 32216

Re: K041381
Trade/Device Name: MetroPack™ Bioresorbable Nasal Dressing and Sinus Stent
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA
Dated: September 2, 2004
Received: September 3, 2004

Dear Mr. Dodd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K041381

Device Name: MeroPack™ Bioresorbable Nasal Dressing and Sinus Stent

Indications For Use

MeroPack™ Bioresorbable Nasal Dressing and Sinus Stent is indicated for use in patients undergoing nasal/sinus surgery as a space occupying stent to separate and prevent adhesions between mucosal surfaces during mesothelial cell regeneration in the nasal cavity; to help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and to prevent lateralization of the middle turbinate during the postoperative period.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or Over-the-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K041381